FDA Sessions a Big Hit at SNM 2006

Representatives from the Food and Drug Administration (FDA) moderated 2 exciting educational sessions at SNM's 2006 Annual Meeting in San Diego, CA, on June 5. During the extremely popular FDA sessions, more than 200 molecular imaging researchers and radiopharmaceutical manufacturers had a rare opportunity to greet FDA staff and hear firsthand how to properly guide items through the Radioactive Drug Research Committee (RDRC) or Investigational New Drug (IND) processes.

George Mills, MD, MBA, division director of FDA's medical imaging and hematology products, was on hand for the "Division of Medical Imaging Update," which featured presentations by Mills and several other division representatives. This FDA division is responsible for the review and approval of diagnostic imaging drugs, diagnostic imaging biologics, radiolabeled therapeutic oncologic drugs and biologics, and nononcology hematology drugs and biologics.

Presenters and their topics included: Mills, "Imaging Biomarkers and Imaging Standardization for Clinical Trials"; Alex Gorovets, medical officer, "Development of Imaging Products: Regulatory Perspective"; Kyong Kang, chief project manager, "Highlights of Standard Meetings with the Medical Imaging Division"; Tiffany Brown, project manager, "Navigating the Process of Imaging Submissions"; and Tushar Kokate, pharmacologist/toxicologist, "Exploratory IND Studies in Humans: Preclinical Requirements."

At the FDA Business Meeting speakers and topics discussed were: Mills, "Introduction"; Thuy Nguyen, regulatory health project manager, "The Administrative Process of Submitting PET Drug Applications"; Ravindra Kasliwal, PhD, premarketing assessment and manufacturing expert, "Chemistry, Manufacturing, and Controls for PET Drug Products"; Renee Tyson, regulatory project manager, "In-Human Studies: RDRC versus IND"; and Orhan H. Suleiman, MS, PhD, senior science policy advisor, "RDRC: 2006 Update."

SNM will continue to invite FDA officers to future annual meetings, as the popularity of the San Diego sessions was indicative of the enormous demand within the molecular imaging/nuclear medicine community for such activities.

The slides/presentations from the FDA sessions may be downloaded from www.snm.org/am.

Hugh Cannon
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NAS "State of the Science in Nuclear Medicine" Project

The National Academy of Sciences (NAS) expert committee working on the State of the Science in Nuclear Medicine project got together in Washington, DC, on June 12 and 13 for the first of several planned meetings. The official mission of the project is to provide findings and recommendations on the following issues:

- Future needs for radiopharmaceutical development for the diagnosis and treatment of human disease;
- Future needs for computational and instrument development for more precise localization of radiotracers in normal and aberrant cell physiologies;
- National impediments to the efficient entry of promising new radiopharmaceutical compounds into clinical feasibility studies and strategies to overcome them; and
- Impacts of shortages of isotopes and highly trained radiochemists on nuclear medicine research, and short- and long-term strategies to alleviate these shortages if they exist.

With that mission in mind, the committee will examine the Department of Energy Office of Science/Office of Biological and Environmental Research Medical Applications and Measurement Sciences program and make recommendations to improve its research and isotope production impacts on nuclear medicine.

To learn more about the NAS State of the Science in Nuclear Medicine project, please visit the National Academies Web site at www.nationalacademies.org.